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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,977	KIEL ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,31-38,40-48,53-58 and 60-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,31-38,40-48,53-58,60-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21, 31-38, 40-48, 53-58 and 60-64 are presented for examination.

Applicant's Amendment filed October 2, 2007 has been received and entered into the present application.

Claims 1-21, 31-38, 40-48, 53-58 and 60-64 remain pending and under examination. Claim 59 is cancelled and claims 1, 3, 12, 31-32, 42, 53, 56 and 63 are amended.

Applicant's arguments, filed October 2, 2007, have been fully considered. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 31-38, 40-48 and 53-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 1, 31 and 53 now recite that step (a) of the process by which the composition is formed is directed to the dissolution of the salt of said active pharmaceutical ingredients in a first solvent to form a first solution, wherein said active pharmaceutical ingredients are dissolved under conditions that will not cause decomposition of said active pharmaceutical ingredients including pH in a range from about 3 to about 11.

In particular, it is noted that the word "including" in the claim limitation directed to "wherein said active pharmaceutical ingredients are dissolved under conditions that will not cause decomposition of said

active pharmaceutical ingredients including pH in a range from about 3 to about 11" fails to clearly set forth whether the pH range is merely an exemplary limitation of the conditions under which dissolution may occur and not cause decomposition of the active pharmaceutical ingredients or whether this pH limitation is, in fact, a required limitation of the claim. As a result, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the metes and bounds of the subject matter for which Applicant is presently seeking protection. Clarification is requested.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21, 31-38, 40-48, 53-58 and 60-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordziel (U.S. Patent No. 6,287,597; 2001) in view of Venkataraman (U.S. Patent No. 6,509,492; 2003), Chopdekar et al. (U.S. Patent No. 5,559,846l 1997) and Singh et al. (U.S. Patent No.

5,759,579; 1998), each already of record, for the reasons of record set forth at pages 10-14 of the previous Office Action dated June 1, 2007, of which said reasons are herein incorporated by reference.

Newly amended claims 1 and 53 now require the presence of a dispersing agent (claims 1 and 53) as part of the claimed composition. Gordziel et al. teaches the use of magnesium aluminum silicate (i.e., "the dispersing agent" as recited in instant claim 5) as part of the carrier used in the disclosed and exemplary suspension formulation (col.2, l.53-col.3, l.20; Example 2).

Newly amended claim 31 now requires the presence of a dispersing agent and a diluent as part of the claimed composition. Gordziel et al. teaches the use of methylcellulose powder (i.e., the "dispersing agent" as recited in instant claim 34, which provides for a "cellulose compound" as the dispersing agent), as well as the use of generic "diluents" as part of the tablet formulations. Please see Gordziel et al., col.2, l.23-50. Though Gordziel does not specifically disclose the use of, e.g., lactose or microcrystalline cellulose, as components of the disclosed tablet formulation (see, e.g., instant claim 36), Venkataraman teaches various carriers or excipients for oral administration that include, for example, corn starch, lactose, magnesium stearate, microcrystalline cellulose, povidone, etc., which are described as biologically inactive and can be administered to patients without causing deleterious interactions with the therapeutic agent(s) (col.5, l.66-col.6, l.12). One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to incorporate any one or more of such ingredients as a pharmaceutically acceptable carrier or excipient in the oral tablet formulation of Gordziel in combination with Venkataraman to facilitate the manufacture and preparation of such a tablet. Such a person would have been motivated to use any one or more of these carriers and/or excipients in light of their biological inactivity and lack of biological interaction with the claimed therapeutic agents.

Newly amended claims 1, 31 and 53 now recite additional limitations of the process by which the claimed composition(s) are produced. Specifically, the claims now require the dissolution of a salt of the active pharmaceutical ingredients in the first process step (where previously either a salt or free base of

the active pharmaceutical ingredients could have been used); the stipulation that the active pharmaceutical ingredients are dissolved in the first process step under conditions that will not cause decomposition of said active pharmaceutical ingredients, including pH in a range from about 3 to about 11; and further that the tannate salts of the active pharmaceutical ingredients are not purified nor dried subsequent to formation. Due to the fact that each of these newly added or amended limitations are clearly directed to further limiting the process by which the product is made and not the product itself, the present amendments to the process fail to patentably distinguish the claimed product in a material, physical or structural manner over that suggested by the prior art. Applicant is again reminded that the patentability of the claimed product is not dependent upon the manner in which it is produced unless the process changes the product. Given the fact that the cited prior art to Chopdekar et al. demonstrates that the art was well aware of methods of production that produce high purity levels of the active ingredients (i.e., at least 99% purity) aside from Applicant's claimed process that allegedly also produces a highly pure product, Applicant's claimed method of production does not appear, on its face, to ultimately produce a different product (tannate salts of the active ingredients with high degree of purity) than what is instantly claimed, though the instantly claimed process may very well differ from that of Chopdekar et al.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Gordziel et al. only discusses the combination of two sympathomimetic drugs (i.e., pyrilamine and phenylephrine), not the combination of sympathomimetic drugs and other non-sympathomimetic drugs, such as antitussives, expectorants, etc. Applicant asserts that the citation to Venkataraman does not remedy the deficiencies of Gordziel et al. because the Venkataraman reference discloses at least ten different combinations including two or more pharmaceutical classes. Applicant alleges that the skilled artisan would have been just as likely to select a composition consisting of an antihistamine and an expectorant as they would have been to select a

composition comprising an antihistamine, a decongestant and an antitussive. Still further, Applicant submits that the artisan would have "had at least a 90% change of being distracted by the Venkataraman teaching wherein a completely different combination of ingredients may have been considered" and asserts that, because the instantly claimed antihistamine is not among those preferred by Venkataraman, the likelihood that one would arrive at the instantly claimed combination is "not as reasonable as the Examiner contends" (Applicant's remarks, p.14-15). Applicant alleges that the Examiner has employed hindsight to arrive at the instant invention, and further argues that Chopdekar et al. teaches the use of phenylephrine free base, and not a salt of phenylephrine. Applicant contends that the reactions of Chopdekar et al. and that of the instant claims are clearly not the same and, therefore, "one cannot reasonably expect that the products will be the same" (Applicant's remarks, p.16). Applicant submits that the instantly claimed process achieves very high yield rate using salts of the active pharmaceutical ingredients, in contrast to the disclosure of Chopdekar et al., which Applicant further alleges is limited to the preparation of phenylephrine tannate only. Lastly, Applicant alleges that Singh et al. is directed to the suspension of already formed solid pharmaceutical salts and fails to disclose the specific combination of phenylephrine, pyrilamine and dextromethorphan in a high purity composition wherein the tannate salts of each active ingredient are produced *in situ*.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, Applicant appears to be under the presumption that there is no motivation to combine a non-sympathomimetic drug (such as, e.g., the antitussive component of Venkataraman) with two sympathomimetic drugs (i.e., pyrilamine tannate and phenylephrine tannate) as disclosed by Gordziel et al. However, the fact that the three components may not necessarily share the same mechanism of action as a sympathomimetic agent does not negate the fact that combinations of two or more compounds (in the instant case, three compounds consisting of phenylephrine tannate, pyrilamine tannate and

dextromethorphan tannate) may be made for other valid reasons that flow logically from the teachings of the prior art that are not relevant to their mechanism of action. In particular, the present combination is clearly not made based on a common or shared mechanism of action, but rather based upon a common and shared therapeutic effect, i.e., that each is known for treating viral infections, cold symptoms, allergic rhinitis, runny nose, cough, post-nasal drop, rhinorrhea and sinusitis. These conditions are known to generally occur together as a result of, for example, the common cold virus, and, thus, the motivation to combine the three elements (i.e., phenylephrine tannate, pyrilamine tannate and the antitussive agent dextromethorphan tannate) flows logically from the fact that each component was known to be administered for a common therapeutic purpose and that the combination of all three agents would clearly result in a single composition with broader therapeutic effects and enhanced benefit to the patient.

Note that the addition of Venkataraman supports the *prima facie* obviousness of the instantly claimed composition in view of the fact that the reference specifically discloses an antitussive composition of dextromethorphan tannate, as well as a preferred tannate composition comprising an antihistamine, decongestant and antitussive [of which the species pyrilamine tannate (antihistamine), phenylephrine tannate (decongestant) and dextromethorphan tannate (antitussive) are expressly disclosed as species of each genus] for the same therapeutic purpose. Please see Table 1, col.7, l.52-col.8, l.15 and col.10, l.4-13. Accordingly, the motivation to add the antitussive component (i.e., dextromethorphan tannate) to the disclosed composition of Gordziel et al. flows logically from the fact that both the composition of Gordziel et al. and that of Venkataraman were each known for the same therapeutic purpose and, furthermore, Venkataraman explicitly discloses the combination of an antihistamine, decongestant and antitussive as a preferable combination of agents out of all of the classes of agents (and, thus, possible combinations) disclosed by the reference.

Though Applicant submits that, "It is unclear how the Examiner knew that the preferable combination in Venkataraman is an antihistamine, a decongestant and an antitussive when Venkataraman

discloses at least ten different combinations including two or more pharmaceutical classes" (Applicant's remarks, p.14), the basis of this argument is unclear in view of the fact that the patentee (not the Examiner) discloses it as a preferable combination. Please see Venkatarman, col.10, l.4-13, which states, "Preferred tannate composition comprising two or more pharmaceutical classes include...an antihistamine, a decongestant and an antitussive...". Accordingly, this teaching clearly supports the fact that the "preferred" status of this combination was explicitly stated in the reference itself and was not, for example, arbitrarily assigned by the Examiner.

Furthermore, the very fact that Venkataraman discloses this combination of an antihistamine, a decongestant and an antitussive agent as a preferable combination places each and every combination of species well within the possession of the skilled artisan. Venkataraman discloses a list of possible antihistamine agents, two possible decongestant agents and a single antitussive agent (see Table 1, cols.6-7) from which to elect various species to form various combinations. The unambiguous disclosure of each individual antihistamine (of which pyrilamine tannate is explicitly disclosed) or each individual decongestant agent (of which phenylephrine tannate is explicitly disclosed) as functional equivalents is clearly indicative of the fact that it would have been obvious, in a self-evident manner, and further in view of the preferable nature of the antihistamine-decongestant-antitussive combination, to employ *any one* of the disclosed antihistamines with *any one* of the two disclosed decongestants with the *one* disclosed antitussive agent, which clearly provides for the instantly claimed combination.

It is also immaterial that Venkataraman may favor other antihistamines, such as, e.g., chlorpheniramine, brompheniramine and diphenhydramine (col.7, l.43-57), over pyrilamine tannate. The disclosure of favorable antihistamines (e.g., chlorpheniramine, brompheniramine and diphenhydramine) does not constitute a teaching away from pyrilamine tannate simply because it is less preferable than the others. Applicant is reminded that the disclosure of a reference must be considered as expansively as is reasonably possible to determine the full scope of the disclosure and, as a result, is most certainly not

limited to that which is preferred. Please see MPEP at §2123, which states, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments...Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments." Thus, the fact that Venkataraman may prefer to use chlorpheniramine, brompheniramine or diphenhydramine as the antihistamine agent does not negate the broader teaching of the reference, which expressly provides for, and, thus, clearly contemplates the use of, pyrilamine tannate as the antihistamine agent of the disclosed composition, absent factual evidence to the contrary.

Given these clear teachings from the cited prior art, Applicant's allegations that the Examiner has used hindsight to reconstruct the instant invention are not persuasive because the rejection relies solely on the knowledge that was generally available to one of ordinary skill in the art at the time of the invention and does not rely improperly upon Applicant's disclosure. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge that was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. Please see *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant further contends that the process by which the instantly claimed product is made is different from that of the cited reference to Chopdekar et al. and, as a result, "one cannot reasonably expect that the products will be the same" (Applicant's remarks, p.16). However, though it is agreed that the process of Chopdekar et al. differs somewhat from the process instantly claimed, Applicant is once again reminded that the instant claims are "product-by-process" claims, and, thus, the invention as claimed is the "product" of phenylephrine tannate, pyrilamine tannate and dextromethorphan tannate. Process limitations *only become patentable distinctions if they confer upon the product a physical or structural property that is not found in the composition of the prior art.*

In the instant case, Applicant asserts that the instantly claimed process achieves a very high yield rate using salts of the claimed active pharmaceutical ingredients (i.e., pyrilamine, phenylephrine and dextromethorphan) as compared to the process disclosed by Chopdekar et al. However, this property of greater yield (in fact, of at least 99% purity) is already present in the composition of the prior art as taught by the combination of references. The synthetic process disclosed by Chopdekar et al. produces phenylephrine tannate [which, *notably*, is a process that Venkataraman expressly references for use in producing tannate salts of the other disclosed active ingredients, e.g., pyrilamine and dextromethorphan (see Venkataraman, col.6, l.39-47) and, therefore, the process of Chopdekar et al. is not (contrary to Applicant's allegation) limited solely to the production of phenylephrine] with at least 99% purity. This clearly meets the allegedly distinguishing characteristic of the instantly claimed product produced by the instantly claimed process, i.e., that the claimed process produces a high yield of the claimed product. Furthermore, if the skilled artisan were to employ the tannate salt production process as disclosed by Chopdekar et al. to form each of the tannate salts of each of the three active ingredients (i.e., pyrilamine, phenylephrine and dextromethorphan) as suggested by the cited combination of references to Gordziel et al. and Venkataraman et al., then the combination and mixing of three essentially pure compounds (each of at least 99% purity) would necessarily produce a single composition with an exceptional level of purity (i.e., substantially free from degradation products and organic solvents) and a consistent level (i.e., uniformity) of total active pharmaceutical content in the final product.

Accordingly, though it may very well be true that the process of Chopdekar et al. is, in fact, different from that presently claimed, the fact remains that the products obtained from either the process of the prior art (i.e., Chopdekar et al.) or the process instantly claimed are substantially identical for the reasons explained *supra*. In view of this rationale, the burden is now shifted to Applicant to demonstrate that the products are, in fact, not identical or substantially identical. This is corroborated by the MPEP at §2113, which states, "Once the Examiner provides a rational tending to show that the claimed product

appears to be the same or similar to that of the prior art, although produced by a different process, *the burden shifts to Applicant to come forward with evidence establishing an unobvious different between the claimed product and the prior art product.*" (emphasis added)

This required evidence, however, is not satisfied merely by Counsel's contention that the reaction of the prior art and that of the instant claims are not the same and, therefore, one would not have reasonably expected that the products would be the same. Such an assertion is an unsupported allegation and fails to take the place of evidence in the record. Statements of this nature are clearly unpersuasive in accordance with the guidance provided at MPEP §2145, which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)". Accordingly, in the absence of this showing, it is respectfully maintained that Applicant has failed to demonstrate how and/or why the instantly claimed process of producing tannate imparts a physical or structural property to the resultant product that is *not* found in the corresponding product of the prior art.

Moreover, for completeness of the record, though Applicant continues to insist that Chopdekar et al. is solely limited to the use of the free base of the active ingredient (Applicant's remarks, p.15-16) to produce the tannate salt, it is herein noted that Chopdekar et al., in fact, is *not* limited in this manner. Please see Chopdekar et al. at col.2, l.42-53, which states:

"The phenylephrine tannate compositions of the invention are prepared by a novel synthetic route. The phenylephrine in the form of its free base is contacted with tannic acid in the presence of water by stirring at a temperature of 20°-80°C for a period of time ranging from minutes to one hour. In the event that the phenylephrine is present as the salt, e.g., the hydrochloride, it is dissolved in cold water and neutralized with a stoichiometric amount of a base such as sodium or potassium hydroxide. The phenylephrine free base precipitates out, recovered by filtration, washed with cold water until all chloride salts have been removed and air dried at ambient temperatures."

It is clear from the disclosure of Chopdekar et al. presented *supra* that the disclosed method of production contemplates the use of either the free base of the active ingredient or, alternatively, use of a salt (e.g., hydrochloride) of the active ingredient that is treated in such a manner to recover the free base form to proceed with the remainder of the process.

Lastly, Applicant's remarks with regard to the Singh et al. reference have been carefully considered, but are also not persuasive. Applicant contends that Singh et al. is directed to the suspension of already formed solid pharmaceutical salts but fails to disclose the specifically claimed combination of phenylephrine, pyrilamine and dextromethorphan in a high purity composition wherein the tannate salts of each active ingredient are produced *in situ*. However, Singh et al. was cited solely for its teaching of a pharmaceutically acceptable liquid excipient suspending base for homogenous suspension of solid pharmaceutically active compounds (notably for antihistamines, decongestants, antitussives, etc.) in the absence of excessive foam formation, which increases shelf life and decreases degradation of the final product. The reference, however, was not relied upon (or alleged to contain a teaching of) the instantly claimed invention *in its entirety*. Applicant is reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Accordingly, since Applicant has failed to address the teachings of Singh et al. as they were combined with the other cited references, Applicant's remarks directed to Singh et al. alone are not persuasive in establishing the non-obviousness of the instantly claimed product.

For these reasons, and those previously made of record at pages 10-14 of the Office Action dated June 1, 2007, rejection of claims 1-21, 31-38, 40-48, 53-58 and 60-64 remains proper and is **maintained**.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy

reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, 31-38, 40-48, 53-58 and 60-64 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-21 and 31-48 of copending U.S. Patent Application No. 10/047,578, for the reasons of record set forth at pages 17-20 of the previous Office Action dated June 1, 2007, of which said reasons are herein incorporated by reference.

Applicant states that submission of a Terminal Disclaimer will be considered when the obviousness-type double patenting rejection is the only rejection remaining in the present case and if the present claims are an obvious variation of the invention of the '578 application.

In view of the fact that the obviousness-type double patenting rejection is not the only rejection remaining in the instant case (see *supra*), and further in the absence of any remarks regarding the rejection or a Terminal Disclaimer in the record, the instant rejection remains proper and is **maintained**.

Conclusion

Rejection of claims 1-21, 31-38, 40-48, 53-58 and 60-64 remains proper and is **maintained**.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

December 3, 2007

12/5/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER